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Medtronic

DBS™

3387

Lead Kit for Deep Brain Stimulation

3389

Implant manual

Rx Only

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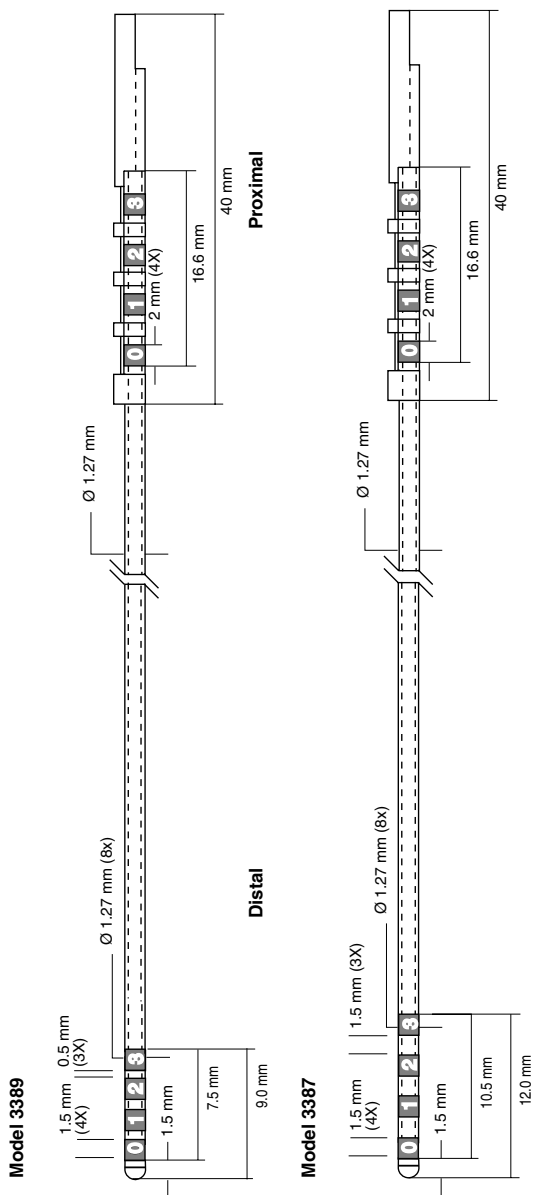


Figure A. Model 3387 and 3389 DBS Leads

Note: All dimensions are approximate.

System Description

The Medtronic Activa System is an implantable, multiprogrammable quadripolar system that delivers electrical stimulation to selected areas of the brain.

The power source of the Activa System, either the Model 7426 Soletra or the Model 7424 Itrel II¹ Neurostimulator, generates electrical signals that are transmitted to the brain. These signals are delivered from the neurostimulator to the brain via the Model 7482 DBS Extension or the Model 7495 Extension, and the Model 3387 or the Model 3389 DBS Lead. These components comprise the implantable portion of the Activa System.

The Medtronic Model 3387 and 3389 DBS Leads are designed to electrically stimulate specific areas of the brain. The Model 3387 DBS lead features wide (1.5 mm) spacing between each of the four electrodes at the distal end (Figure A). The Model 3389 DBS lead features narrow (0.5 mm) spacing between each of the four electrodes at the distal end (Figure A). The physician may choose the Model 3387 DBS lead to provide electrodes spread over 10.5 mm or the Model 3389 DBS lead to provide electrodes spread over 7.5 mm.

The neurostimulator is comprised of electronic circuitry and a battery, which are hermetically sealed in a titanium case.

Indications

Medtronic Activa Therapy includes Activa Parkinson's Control Therapy and Activa Tremor Control Therapy.

Parkinson's Control Therapy

Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic Activa Parkinson's Control Therapy is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Tremor Control Therapy

Unilateral thalamic stimulation by the Medtronic Activa Tremor Control System is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

¹ The Itrel II Neurostimulator is used for Tremor Control Therapy only.

Contraindications

Implantation of an Activa Brain Stimulation System is contraindicated for:

- Patients exposed to diathermy. Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned “on” or “off.” Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.

- Patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area. Refer to “Appendix: MRI and Activa Therapy” on page 53 for comprehensive safety information.
- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the brain stimulator.

Warnings

Coagulopathies – Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Avoid Excessive Stimulation – There is a potential risk of brain tissue damage for stimulation parameter settings of high amplitudes and wide pulse widths.

The Activa System is capable of parameter settings out of the range of those used in the clinical studies. Suppression of symptoms should occur at amplitudes of 1 to 3.5 V, pulse widths of 60 to 120 μ sec, and rates of 130 to 185 Hz. Higher amplitudes and pulse widths may indicate a system problem or less than optimal lead placement. Parameter values exceeding the recommended output settings should only be programmed with due consideration of the warnings concerning charge densities and charge imbalance described in “Programming the Neurostimulator” on page 42. If programming of stimulation parameters exceeds charge density limits, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE. CONSULT TECH MANUAL. PRESS CLEAR TO CONTINUE.**

If a lead is implanted in the thalamus, the use of rates less than 30 pps may “drive” tremor, i.e., cause it to occur at the same frequency as the programmed frequency. For this reason, rates should not be programmed below 30 pps when the lead is implanted in the thalamus.

Case Damage – If the neurostimulator case is ruptured or pierced after implant due to outside forces, severe burns could result from exposure to battery chemicals.

Placement of Lead-Extension Connector in Neck – Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture.

Theft Detectors and Screening Devices – Theft detectors found in retail stores, public libraries, etc., and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch On or Off. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients as they pass through these devices. Refer to “Patient Counseling Information” on page 48 for more information.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to “Physician Training Information” on page 47 in this manual for further information.

Prescribing Physicians – Prescribing physicians should be experienced in the diagnosis and treatment of movement disorders and should be familiar with the use of the Activa System.

Storage and Sterilization

Resterilization Considerations – Refer to “Resterilization” on page 18 for further information.

Storage Temperature – Store the DBS Lead between -30° F (-34° C) and 135° F (57° C). Temperatures outside this range can damage components.

System and Therapy

Battery Longevity and Brain Target Selection – Stimulation settings for systems implanted in the internal Globus Pallidus (GPi) may be higher than stimulation settings for systems implanted in the Subthalamic Nucleus (STN). Consequently, systems implanted in the GPi may have shorter battery life than systems implanted in the STN.

Component Failures – The Activa System may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical short or open circuits, conductor (wire) fracture, and insulation breaches, cannot be predicted.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Inadvertent Programming – If more than one neurostimulator is implanted, then the potential for unintentional programming changes to the other neurostimulator exists. If two neurostimulators are implanted, they must be implanted at least 8 inches apart to minimize interference. Verify final programmed parameters by reviewing both devices at the conclusion of any programming session.

Lead Materials – The polyurethane tubing of the lead may release neurotoxic or carcinogenic compounds. Data are insufficient to assess the likelihood of these effects occurring in patients who receive the device.

Long-Term Safety and Effectiveness of Activa Therapy – The long-term safety and effectiveness of Activa Therapy has not been established.

Magnet-Controlled Amplitude (Model 7424 Itrel II Neurostimulator only) – For Activa Therapy, always program Mag Amp, or Magnet-Controlled Amplitude, to the same value as the normal amplitude setting. If no Mag Amp value is programmed, the amplitude will decrease to zero when Mag Amp is activated, resulting in no stimulation whether the device is On or Off.

Programming Different Neurostimulator Models – The Model 7432 Physician Programmer must be turned off and turned back on before attempting to program a different neurostimulator model (for example, if programming a Soletra Model 7426 neurostimulator immediately after programming an Itrel II Model 7424 neurostimulator). If the programmer is not turned off and on, the programmer will display “NO TELEMETRY, POSITION HEAD AND TRY AGAIN” and the software will not allow the different neurostimulator to be programmed.

Use in Specific Populations – The safety and effectiveness of this therapy has not been established for the following:

- Patients with neurological disease origins other than idiopathic Parkinson’s disease or Essential Tremor
- Patients with a previous surgical ablation procedure
- Patients who are pregnant
- Patients under the age of 18 years
- Patients over the age of 75 years
- Patients with dementia
- Patients with coagulopathies
- Patients with moderate to severe depression

Implantation/Explantation

Body Fluids – Do not resterilize any system component after exposure to body fluids.

Component Disposal – If explanting an Activa System component, please remember the following guidelines:

- Do not incinerate or cremate the neurostimulator; explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

Connections – Wipe off any body fluids on the extension or lead contacts or connector before connecting. Contamination of connections can cause intermittent stimulation or shorts in the neurostimulation circuit.

Connector Block Setscrews – Limit counter-clockwise rotations of neurostimulator setscrews. Rotate enough to provide an unobstructed pathway for the extension connector pins. Too many counter-clockwise rotations may disengage the setscrew from the connector block.

Etched Identification – Place the neurostimulator away from bony structures and with the etched identification side facing outward, away from muscle tissue to minimize pain at the neurostimulator site. This also helps to minimize the possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

Excess Extension Wire – Do not place any excess extension wire on top of the neurostimulator's front side (printed side). Wrap any excess extension wire around the perimeter (Figure 1). This avoids any increase in subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension wire.

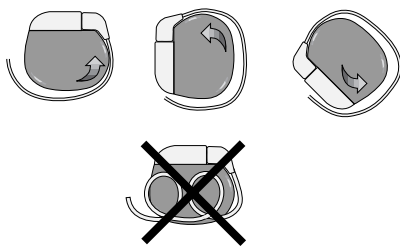


Figure 1. Wrap excess wire around the perimeter of the neurostimulator.

Handling Components – Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by excessive traction or sharp instruments and may require surgical replacement.

- Do not bend, kink, or stretch the lead body whether or not the stylet is in place. Do not bend or kink the tungsten stylet.
- Do not tie a suture directly to the lead body. Use the burr hole cap and ring provided by Medtronic to secure the lead in place.
- When handling the lead with forceps, use only a rubber-tipped bayonet forceps.

Hex Wrench – Do not overtighten setscrews when using the hex wrench. Excessive torque on setscrews may damage lead contacts. Verify that the sealing grommet has closed on the neurostimulator.

Implant Considerations – Do not implant a component of the system when:

- The storage package has been pierced or altered; or if the component shows signs of damage; or
- The “Use By” date has expired, because this can adversely affect storage package sterility.

Multiple Implants – The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

Percutaneous Extension Setscrew Connector – If resistance is still felt when removing lead from the percutaneous extension setscrew connector, loosen the setscrews slightly to ensure that they clear the lead contacts. Avoid disengaging the setscrews. Inspect the lead contacts for damage (flattening or stretching of the lead) if resistance was felt prior to removal.

Percutaneous Extension Severing – When severing the percutaneous extension, use gentle traction on the extension to avoid dislodging the lead.

Percutaneous Extension Suture Removal – Do not cut near the lead when removing sutures from the percutaneous extension. Cutting the lead’s insulation can result in loss of stimulation and the lead’s failure.

Sutures – Do not draw the suture too tightly because damage may occur to either the connector boot or the lead.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various medical or environmental devices. These medical and environmental (home, occupational, and other) devices may generate enough interference to change the parameters of a neurostimulator; turn a neurostimulator off and on, or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead or both to “pick up” electromagnetic interference and deliver an excess voltage, which can in turn deliver an excessive amount of heat to the brain. Refer to the following sections for guidelines on the interaction of electromagnetic interference and an implanted Activa System.

Magnetic Resonance Imaging

Based on tests to date, some MRI procedures can be performed safely with an implanted Activa System. MRI systems used to safely perform MRI include MRI systems operating at 1.5 Tesla (specific MRI machines include Siemens Magnetom 1.5T VISION, Picker International 1.5T Edge, and GE Signa 1.5T Echospeed). The safety of other MRI machines used with implanted Activa Systems is not known.

- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.
- Carefully weigh any decision to perform magnetic resonance imaging (MRI) scans on patients who require the neurostimulator to control tremor. Image quality during MRI scans may be reduced, because the tremor may return when the brain stimulator is turned off.

Use of MRI could possibly result in movement, heating or damage to the implanted Activa System. The MRI image around the implanted lead may be distorted and shadowed. Induced voltages in the neurostimulator and/or lead may occur, possibly causing uncomfortable (“jolting” or “shocking”) levels of stimulation. Clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa System, and refer to “Appendix: MRI and Activa Therapy” on page 53 for comprehensive safety information.

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the Activa System.

Effects on Other Medical Devices – The Activa System may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient’s benefit from each device.

Electrocautery – Electrocautery can damage the lead, the extension, or both. It can also cause temporary suppression of neurostimulator output and/or reprogramming of the neurostimulator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the neurostimulator, extension, and lead as possible, and use of bipolar electrocautery is recommended.

External Defibrillators – If a patient requires external defibrillation, the first consideration should be patient survival. Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a neurostimulator.

If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulator-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

High Radiation Sources – High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, place lead shielding over the device to prevent radiation damage.

Lithotripsy – Use of high output ultrasonic devices, such as an electrohydraulic lithotripter, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Psychotherapeutic Procedures – The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) has not been established.

Home or Occupational Environment

Home Appliances – Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation. However, items with magnets (e.g., stereo speakers, refrigerators, freezers) may cause the neurostimulator to switch On or Off.

Occupational Environments – Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough electromagnetic interference (EMI) to interfere with neurostimulator operation if approached too closely.

Patient Activities/Environmental Precautions – Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch On or Off. The system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices which generate electromagnetic interference, call 1-800-707-0933.

Patient Magnet – The magnet provided to the patient for device activation and deactivation may damage televisions, computer disks, computer monitors, credit cards, and other items affected by strong magnetic fields.

Radio Frequency Sources – Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning On or Off of the stimulation, these devices should be kept at least 4 inches away from the implanted neurostimulator.

Therapeutic Magnets – Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent on or off activations of the neurostimulator. Therefore, patients should be advised not to use them.

Adverse Events

For a complete list of adverse events reported during the Parkinson's disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with this product.

Clinical Studies

For results of the Parkinson's disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with this product.

Individualization of Treatment

For information about individualization of treatment, refer to the *Activa Clinical Summary* packaged with this product.

Resterilization

The lead and accessories of the DBS Model 3387 or Model 3389 Lead Kit were sterilized with ethylene oxide before shipment. Inspect the sterile package for seal integrity and damage to the package before opening and using the contents. If you are unsure of the components' sterility for any reason, they can be resterilized at the hospital site.

Note: If contamination is suspected because of a defective sterile package seal, leads and accessories can be returned to Medtronic for replacement or they can be resterilized at the hospital. Replacements are otherwise subject to the terms of the Medtronic Limited Warranty (U.S. Customers). Medtronic does not accept returned leads or accessories for resterilization and return them to customers.

Due to variations in hospital sterilizers, precise instructions for sterilization or aeration cannot be given here. If further information is necessary regarding the procedures to be used, contact the manufacturer of the sterilizer unit. Use biological indicators or other acceptable methods to assist in validating the effectiveness of the hospital's sterilizer unit.

Medtronic cannot accept the responsibility for the resterilization of any components. If, however, the decision is made to resterilize, usual and customary sterilization methods should be used.



Cautions:

- Do not resterilize and use the leads or the accessories after exposure to body tissues or fluids.
- Do not use radiation to resterilize any component. Do not autoclave the lead, percutaneous extension, burr hole ring and cap, connector boot, or stylet.

Subject to the foregoing, the following may be considered:

Table 1 summarizes the resterilization options and restrictions. The paragraphs following the table provide additional information.

Table 1. Resterilization Options and Restrictions.

Component	Sterilization Methods ^a		
	Ethylene Oxide 130° F (55° C) Maximum	Autoclave 250° F (121° C) 15 psi 30 minutes	“Flash” Autoclave 270° F (132° C) 26 psi 5 minutes
Lead	YES	NO	NO
Percutaneous Extension	YES	NO	NO
Stylets	YES	NO	NO
Screening Cable	YES	YES ^b	YES ^c
Burr Hole Ring/Cap Connector Boot	YES	NO	NO
Hex Wrench	YES	YES	YES
Depth Stop Gauge	YES	YES	YES
Tunneling Tool/Tip	YES	YES	YES
PTFE Tubes	YES	YES	YES

^a Medtronic cannot accept responsibility for the resterilization of any components at the hospital.

^b 60 minutes

^c 30 minutes

Ethylene oxide is an acceptable method for resterilization when the leads and accessories are repackaged in an ethylene oxide-permeable package. The temperature during the process should not exceed 130° F (55° C). The maximum possible aeration must be allowed before implanting the lead and using the accessories.

Steam autoclaving may also be used as a sterilization method for components marked YES for autoclave or “flash” autoclave in Table 1. For autoclave, a standard cycle of 30 minutes at 250° F (121° C) and 15 psi is recommended. For “flash” autoclave, a standard cycle of 5 minutes at 270° F (132° C) and 27 psi is recommended. Do not sterilize a component using any method that is marked NO for that component.

Directions for Use

The implantation of the DBS Lead requires stereotactic neurosurgical techniques for the initial implant and ongoing postoperative patient management (refer to page 39). Medtronic recognizes that a variety of approaches may be used to accomplish this. The following outline is presented as one possible approach for the physician's consideration.

The target site may be localized for stereotactic implantation of the DBS Lead using CT scans, MRI, or ventriculography. A test stimulation or mapping electrode may then be utilized for further localization of the target with electrical stimulation. Neurosurgeons who use microelectrode recording in stimulation techniques may choose commercially available microelectrodes such as Radionics, Inc., MicroNeurode™, and FHC, Inc., microTargeting® electrodes. The DBS lead is not recommended for mapping.

Target sites for Tremor Control Therapy and Parkinson's Control Therapy include the ventral intermediate nucleus of the thalamus (Vim), and the subthalamic nucleus (STN) or the internal globus pallidus (GPi) respectively (Table 2).

Table 2. *Indications for Target Sites.*

Target Site	Indication
STN/GPi	Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic Activa Parkinson's Control Therapy is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.
Vim	Unilateral thalamic stimulation by the Medtronic Activa Tremor Control System is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Lead Implant Procedure



Caution: The stylet inserted in the Model 3387 or 3389 DBS Lead is matched specifically to that individual lead; stylets are not interchangeable between 3387 and 3389 Lead models or between individual leads of the same model.

To implant the DBS Lead, an insertion cannula and stylet should be placed to a point approximately 15 mm proximal to the target site for stimulation. The lead should be passed through the insertion cannula and advanced to the target site. To stabilize the lead in the insertion cannula, use the Model 3354 Lead Frame Kit (for Leksell stereotactic frames), or the Model 3353 Lead Frame Kit (for Radionics stereotactic frames).

The following steps outline the suggested lead implant procedure:

1. After placement of the stereotactic frame, use standard imaging techniques to determine coordinates for the lead's target site.
2. Prepare the patient per normal stereotactic neurosurgical techniques.
3. Make a skin incision, with consideration given to burr hole placement.
4. Prepare a subgaleal pocket by blunt dissection at the top of the skull at the edge of the burr hole incision for placement of the excess lead wire and connector.

Note: Placement of the pocket may be on either the left or right side of the skull.

5. Place a 14 mm diameter burr hole in the desired location.

Note: Medtronic recommends using a straight-edged 14 mm perforator to form the burr hole.



Caution: Use only the burr hole cap and ring packaged with this lead to anchor the lead. The safety, effectiveness, and possible effects to the Activa System of other methods (i.e. glues, cements, surgical plates) have not been established.

6. Place the burr hole ring tightly against the bone in the burr hole, using your finger and a curved mosquito hemostat.
7. Attach the lead holder assembly to the stereotactic frame, positioning the guide tube or collimator so that its distal end is 1.25 to 2.5 cm from the skull (Figure 2).

Note: Refer to the Model 3353 (Radionics) or Model 3354 (Leksell) Lead Frame Kit Instructions.

8. Insert stylet into cannula.
9. Advance the insertion cannula through the guide tube to a point approximately 15 mm proximal to the lead's target site.
10. Remove stylet from cannula.

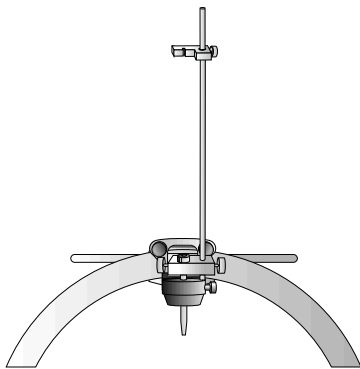


Figure 2. Attach lead holder assembly to frame.

11. Determine target location with a test electrode.
 - a. Place test electrode 10 mm above target. Slowly advance it 1 mm at a time and test stimulate. Maximum therapeutic effect with minimum side effects indicate the appropriate target.
 - b. Once target is determined, document the location.
- Note:** It may be necessary to make additional tracks to achieve optimum lead placement. However, additional tracks should be minimized to reduce the risk of hemorrhage.
12. Remove the test electrode. Determine the depth of placement for the DBS Lead.
 13. Attach the lead depth stop gauge on the lead at the point calculated in Step 12.
 14. Attach proximal end of the lead to the lead holder to within 2.5 cm of the stylet handle.
 15. Advance the lead slowly along the track made by the test electrode.



Caution: An increase in resistance or friction during lead insertion may indicate that the lead is deviating from the intended track. If this occurs, pull the lead back and re-advance until target is reached.

Intraoperative Stimulation Test

This section outlines the intraoperative stimulation test that helps confirm the desired lead position for optimum symptom suppression and minimization of side effects. This test requires the following components:

- A Model 3625 Test Stimulator and
- An alligator clip or twist-lock screening cable (provided with the lead).

Note: A spare 9V battery is recommended.

The procedures outlined in this section provide instructions for test stimulation with the alligator clip or twist-lock screening cable and the Model 3625 Test Stimulator. Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions.

To ensure patient eligibility for the Activa Therapy, verify that the screening parameters using the Model 3625 Test Stimulator are within the parameter range available with the Soletra Model 7426 Neurostimulator or the Itrel II Model 7424 Neurostimulator. Refer to Table 3.

Table 3. Programmable Stimulation Parameter Values.

Programmable Parameters	Values
Pulse Amplitude (Peak Voltage)	0 to 10.5 V
Rate	2, 5, 10, 15, 20, 25, 30, 33, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 130, 135, 145, 160, 170, 185 pps
Pulse Width	60, 90, 120, 150, 180, 210, 270, 330, 400, 450 μ sec

Note: High amplitude/pulse width combinations can result in excessive charge density. Refer to “Programming the Neurostimulator” on page 42 for more information.

Test Stimulation with the Alligator Clip Screening Cable

The alligator clip screening cable is bipolar. The polarity of the black alligator clip is controlled by Electrode Switch 0, and the red alligator clip is controlled by Electrode Switch 3. Electrode Switches 1 and 2 on the Model 3625 Test Stimulator are inactive. **Use the alligator clips to select the lead contacts that correspond to the electrodes you want to test. For example, if you want to change the negative electrode from electrode 0 to electrode 1, attach the black alligator clip to the lead contact corresponding to electrode 1.**



Caution: The switches on the 3625 Test Stimulator corresponding to electrodes 0 and 3 must be manually set to establish a circuit. One switch must be positive and the other switch negative. If the 0 and 3 electrode switches are not set accordingly, no stimulation will result. Refer to Figure 6, page 25.

1. Check that the test stimulator External **A**–Amplitude Control (Figure 3) is turned **Off**.

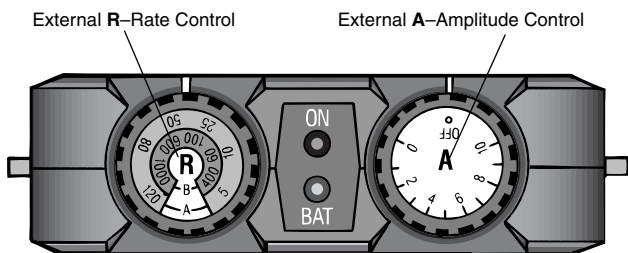


Figure 3. Model 3625 Test Stimulator External Controls.

2. Attach the alligator clips to the applicable lead contacts that correspond to the desired electrodes. Figure 4 provides an example of the connection to the lead contacts for electrodes 0 and 3.

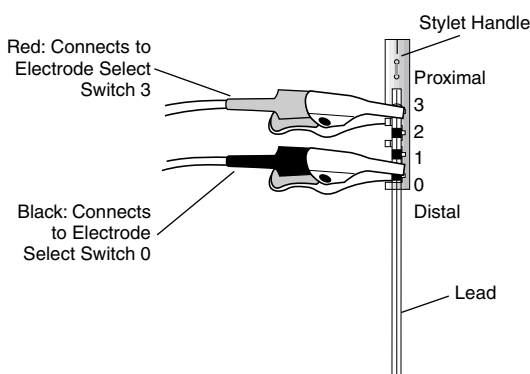


Figure 4. Connect clips to lead contacts.



Warning: Always turn External A—Amplitude Control Off before connecting or disconnecting the screening cable from the test stimulator, or before changing alligator clip connections to the lead contacts to prevent possible uncomfortable patient stimulation.

3. Verify that the test stimulator output (Amplitude) is turned to Off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 5). Note the correct plug orientation, with the cord pointing up. **The plug fits in one way only.** Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions on utilization.

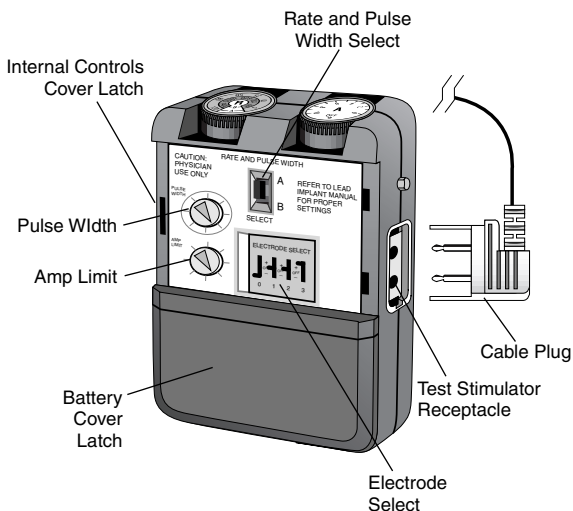


Figure 5. Model 3625 Test Stimulator Internal Controls.

4. Remove the Internal Control Cover and set the Internal Controls (Figure 5) as follows:
 - a. Set the **ELECTRODE SELECT** switch polarities as shown (Figure 6).

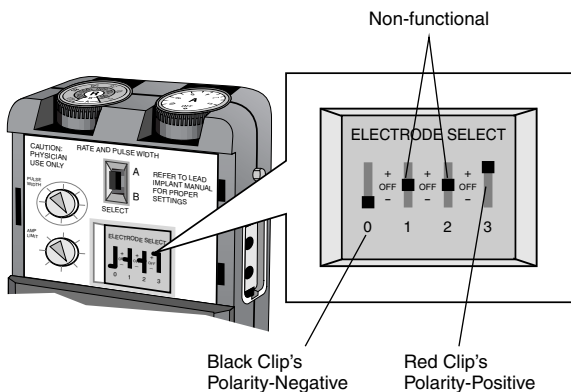


Figure 6. Set Electrode Select switches.

- b. Set the **RATE AND PULSE WIDTH SELECT** switch to **B** (Figure 7).

Note: When the switch is in position B (High Rate, Low Pulse Width):

- Rate = 60–1400 Hz
- PW = 50–250 μ sec

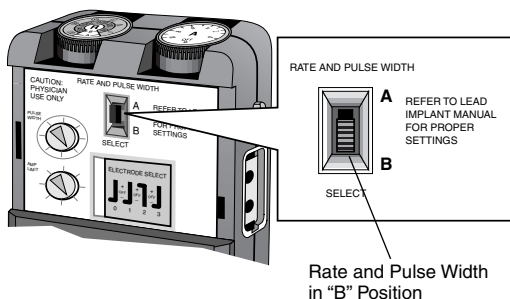


Figure 7. Set Rate and Pulse Width Select to B Position.

- c. Set the External Rate to 130 Hz or as desired (therapeutic range 130-185 Hz).(Figure 8). Do not exceed 185 Hz.

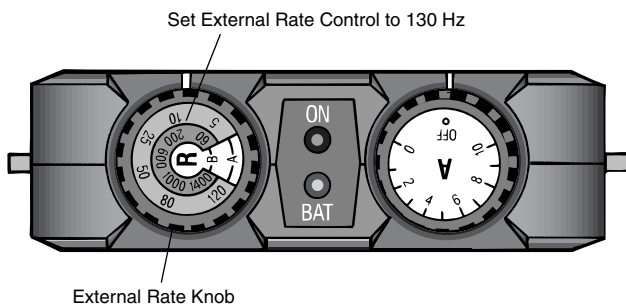


Figure 8. Set External Rate Control to 130 Hz.

- d. Set the PULSE WIDTH control to 60 μ sec or as desired (typical therapeutic range 60-120 μ sec). (Figure 9).

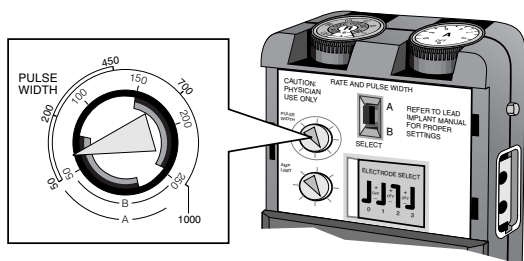


Figure 9. Set Pulse Width to 60 μ sec.

- e. Set the AMP LIMIT control to 10 V, or as desired (Figure 10).

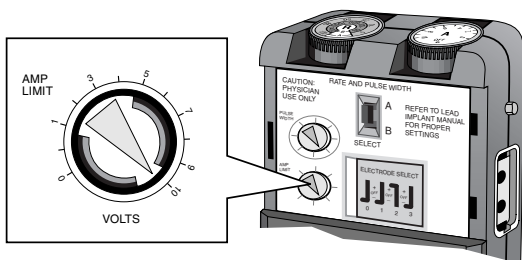


Figure 10. Set Amp Limit to 10 V.

5. Turn the External A—Amplitude Control On and gradually increase it until the patient indicates an effect (average therapeutic range 1.0 to 3.5 volts), or until a stimulation effect such as the suppression of symptoms is noted. **Do not exceed 3.6 volts.**

If the Vim is the targeted nucleus, the desired stimulation effect is an obvious suppression of tremor. Other stimulation effects that may aid in placement of the lead, but may not be desirable, include paresthesia, especially in the hand and around the mouth.

If the GPi or STN is the targeted nucleus, the desired stimulation effect is the obvious suppression of a predominant Parkinson's disease symptom, such as rigidity, bradykinesia, or tremor. Neurological assessments such as the passive movement of joints, finger tapping, hand movements, or holding and drinking from a ceramic cup can be administered to evaluate the effects of stimulation on Parkinson's disease symptoms. Other stimulation effects that may aid in placement of the lead in the STN, but are not desirable, include dystonia and choreic dyskinesias. Other stimulation effects that may aid in placement of the lead in the GPi, but are not desirable, include visual field effects and dystonia.

If test stimulation is unsuccessful or if parameter settings to achieve therapeutic benefit are within the charge density warning area (refer to Figure 30 on page 43), the system should not be implanted.

6. To reverse the output polarity:
 - a. Set the External A–Amplitude Control to Off.
 - b. Set the ELECTRODE SELECT switch polarities as shown (Figure 11).

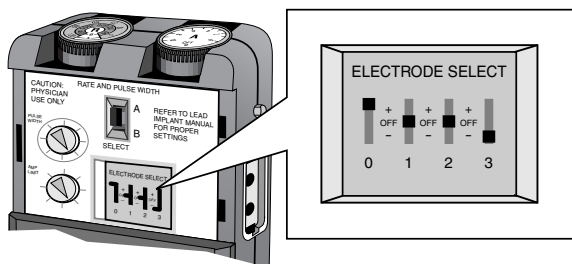


Figure 11. Set Electrode Select switches to reverse polarity.

Note: The output polarity can also be reversed by switching the alligator clip-electrode contact connections.



Warning: Always turn the test stimulator External A–amplitude Control to Off before changing ELECTRODE SELECT switches or other Internal Controls to prevent possible uncomfortable patient stimulation.

7. When the optimum stimulation mode and electrode configuration are determined, and the suppression of the movement disorder has been achieved with a minimum of side effects, turn the test stimulator's External A–Amplitude Control to Off.
8. When finished with the Internal Controls, replace the Internal Controls cover:
 - a. Line up the two hinges with the holes in the test stimulator case.
 - b. Press down on the cover to close it.
9. Disconnect the screening cable alligator clips from the lead contacts and proceed to “Stylet Removal and Lead Stabilization” on page 31.

Test Stimulation with the Twist-Lock Screening Cable

The twist-lock screening cable is quadripolar. When connected to the Model 3625 Test Stimulator, all four Electrode Switches are active.

 **Caution:** Before connecting the twist-lock screening cable to the stylet handle of the DBS Lead, secure the cable to the frame or another stable object. Otherwise, the weight of the twist-lock connector may cause lead movement.

1. Check that the test stimulator output (Amplitude) is Off.
2. Insert and lock the stylet handle on the lead into the twist-lock connector on the screening cable. (Refer to Figures 12-15).

Note: The handle fits into cylindrical twist connector in only one way (Figure 12).

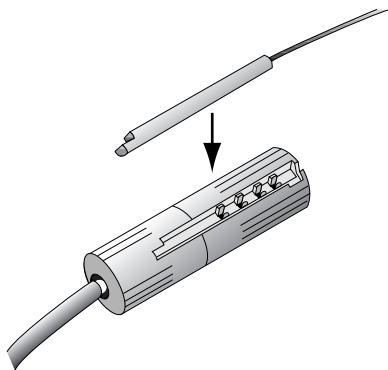


Figure 12. Insert the pin connector into the twist-lock cable.

- a. Place the stylet handle into the groove at a slight angle to secure the handle's end (Figure 13).

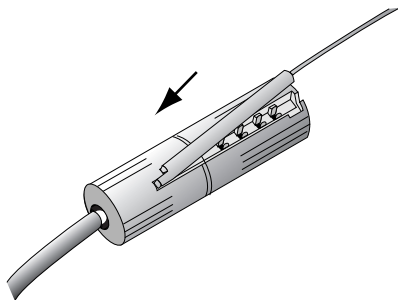


Figure 13. Secure stylet handle's end in groove.

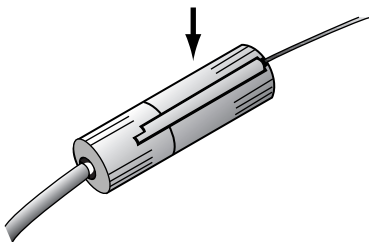


Figure 14. Insert stylet handle into groove.

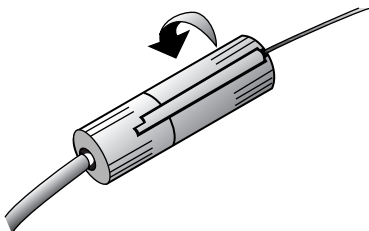


Figure 15. Lock the twist-lock connector.

3. Verify that the test stimulator output (Amplitude) is turned to Off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 16). Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions on utilization.



Warning: Always adjust test stimulator output (Amplitude) to Off before connecting or disconnecting screening cable to prevent possible uncomfortable patient stimulation.

Note: The plug of the screening cable only fits one way into the test stimulator jack.

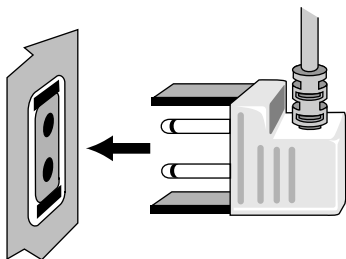


Figure 16. Connect screening cable and test stimulator.

4. Proceed with the test stimulation. Refer to steps 4-6 of Test Stimulation with the Alligator Clip Screening Cable starting on page 25 for stimulation parameter recommendations. **All four electrode switches are active with the twist-lock cable.** Electrode selection and activation is controlled by the switches on the back of the Model 3625 Test Stimulator (refer to Figure 5 on page 25).
5. When finished with intraoperative test stimulation, turn the test stimulator Off.
6. Unlock the cylindrical twist-lock connector and remove the connector handle.
 - a. Hold the test stimulator end of the twist connector stationary in the left hand and turn the lead end of the twist connector clockwise with the right hand until the grooves on each side are lined up (Figure 17).

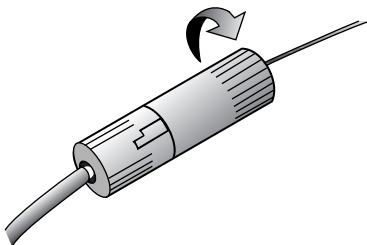


Figure 17. *Unlock the twist-lock connector.*

- b. Gently pull up on lead end of connector handle until it is free to remove it from the twist connector.

When the optimum stimulation mode and electrode configuration are determined, and the suppression of the movement disorder has been achieved with minimal side effects, record the settings, then proceed to Stylet Removal and Lead Stabilization in the next section.

Stylet Removal and Lead Stabilization

When the physician has determined that the lead is properly positioned, the lead may be secured in the burr hole ring.

Complete the following steps to secure the lead in the burr hole ring.

1. Ensure that the DBS Lead is securely fastened in the lead holder groove. The lead holder is provided with the lead frame kit.
 - a. Remove the adjustable depth stop gauge from the insertion cannula, taking care not to dislodge the lead.
 - b. Carefully pull the insertion cannula up until the lead can be seen between the burr hole and the cannula.
 - c. Gently hold the lead at the point it exits the skull. An assistant should hold the insertion cannula to ensure that it stays in position.
 - d. Carefully loosen the stylet handle from the lead (Figure 18).

- e. While keeping the lead secure at the exit site, remove the lead from the lead holder.
- f. Remove the stylet from the lead.
- g. Remove the insertion cannula.
- h. Remove the guide tube assembly.

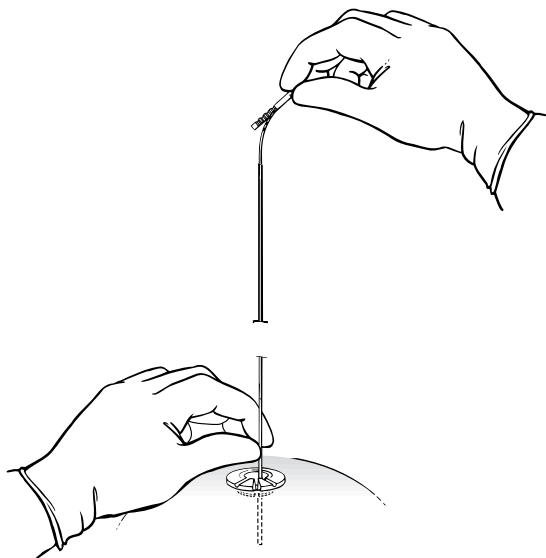


Figure 18. Loosen the stylet handle from the lead.

2. Gently press the lead into one of the precut grooves on the inner side of the burr hole ring, ensuring that the lead exits the burr hole ring on the side which the neurostimulator will be implanted (Figure 19).

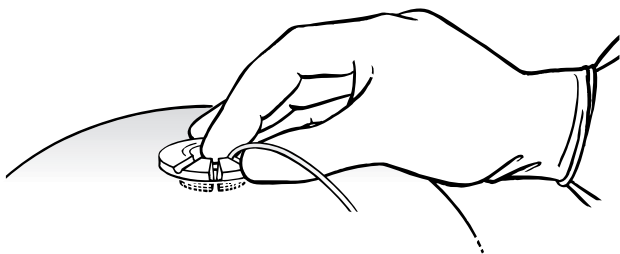


Figure 19. Gently press the lead into the burr hole ring.

3. To minimize the potential for lead movement, place the burr hole cap into the ring as follows:
 - a. Align the tab in the burr hole cap with the slot in the burr hole ring.

- b. Hold the cap tilted toward the slot in the ring where the lead is fixed, and gently press the cap against the edge of the burr hole ring and lead (Figure 20a).
- c. Gently press down on the lead exit side of the burr hole cap while rolling the cap downwards into the ring until secure (Figure 20b).

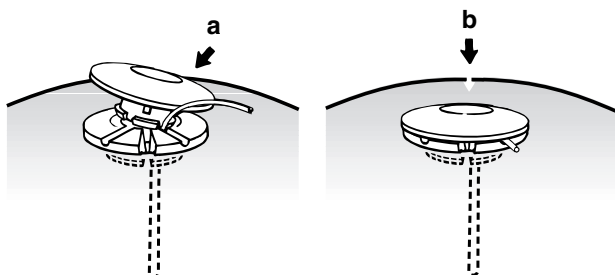


Figure 20. Gently roll burr hole cap into burr hole ring.

4. Recheck the stimulation effect after stabilizing the lead in the burr hole ring and cap.
5. Check that the test stimulator output (Amplitude) is adjusted to **Off**.
6. If using the alligator clip screening cable, carefully attach the alligator clips to the desired connector ring contacts on the lead end.



Warning: Always adjust test stimulator output (Amplitude) to Off when changing alligator clip connections to connector rings to prevent possible uncomfortable patient stimulation.

7. If using the twist-lock screening cable, complete the following steps:
 - a. Attach the enclosed short stylet to the proximal end of the lead (Figure 21).

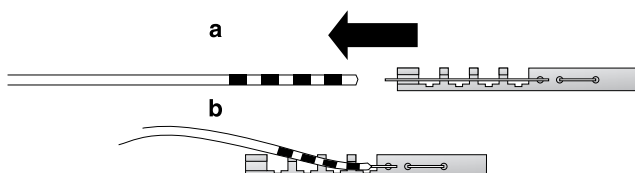


Figure 21. Attach short stylet to lead.

- b. Insert the short stylet completely into the lead (Figure 21a).
- c. Secure the lead in the stylet handle (Figure 21b).

- d. Insert the stylet handle of the lead into the cylindrical twist-lock connector on the screening cable and lock it (Refer to Figures 12 thru 15).

8. Turn on the test stimulator and recheck stimulation effects.

Note: If lead movement has occurred, it may be necessary to remove the lead and repeat the implant procedure, using a new lead.



Warning: If lead repositioning is required, do not reinsert stylet into implanted lead. Use a new lead.

9. Verify lead placement with standard imaging techniques.
10. If a second lead is implanted, repeat the target localization, lead implant, and test stimulation procedures.
11. Prepare the patient for implant of the neurostimulator.

Note: If the remainder of the system is not implanted immediately, place the lead in the subgaleal pocket, close the incision, and apply the appropriate dressing.

Tunneling to the Neurostimulator Site

For instructions on tunneling to the neurostimulator site refer to the appropriate extension manual.

Making the Lead-Extension Connection

For instructions on making the lead-extension connection refer to the appropriate extension manual.

Making the Extension-Neurostimulator Connection

For instructions on making the extension-neurostimulator connection refer to the appropriate extension manual.

Interoperative Test Stimulation

If a postoperative test stimulation period is desired, use the following three procedures for Extended Test Stimulation outlined in this section:

- Create Percutaneous Tunnel
- Connect Lead and Percutaneous Extension
- Perform Interoperative Stimulation Test

Create Percutaneous Tunnel

The following procedure provides instructions for attaching and implanting the percutaneous extension in the lead kit. The implanted wires should exit the skin above the ear during the test stimulation period (Figure 22).

1. Remove the percutaneous extension from its tube. Discard this tube.

- Place one of the shorter tubes packaged with the lead over the tunneling tool. Attach the metal PERCUPASS II Tunneling Tip.

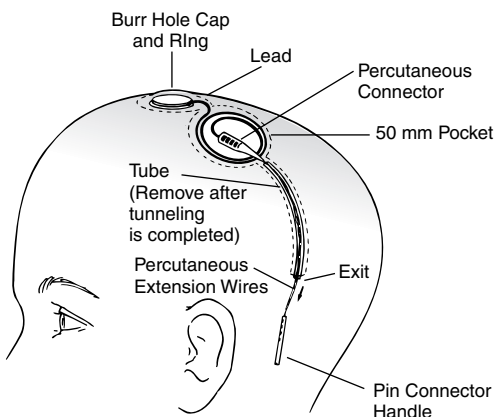


Figure 22. Tunneling and lead placement.

- Make a small stab wound where the percutaneous extension wires will exit the skin.
- Tunnel subcutaneously from the pocket through the exit point.
- Remove the tunneling tool, leaving the tube in place.
- Pass the percutaneous extension wires through the tube. Leave only the pin connector and approximately 40 mm of the fine wires protruding from the exit point (Figure 22).
- Remove the tube.
- Coil the lead in a circle greater than 25 mm in diameter to prevent bending or kinking. Place the coiled lead in the subgaleal pocket.

Caution: Be extremely careful when using sharp instruments around the lead body to avoid nicking or damaging the lead.

Connect Lead and Percutaneous Extension

The following procedure provides instructions on how to connect the DBS Lead to the percutaneous extension.

- Push the connector boot over the exposed end of the lead (Figure 23).

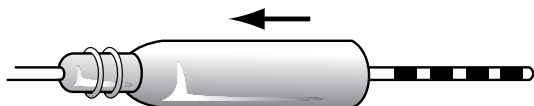


Figure 23. Push connector boot over lead.

2. Wipe off any remaining body fluids from the surface of the lead contacts and the extension connector, then insert the exposed end of the lead completely into the percutaneous extension connector (Figure 24).



Figure 24. Insert lead fully into setscrew junction.

3. Tighten each of the four setscrews by turning them clockwise in the setscrew sockets with the hex wrench provided (Figure 25). Tighten the setscrews only until they touch the contacts. Continue tightening for a maximum of 1/4 turn only.

 **Caution:** Excessive torque on setscrews may damage lead contacts.

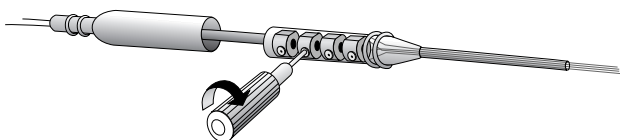


Figure 25. Tighten setscrews.

Note: The setscrews must engage contacts on the lead before stimulation can be attempted.

4. Slide the connector boot into place, completely covering the lead/extension connection.

Note: If it is difficult to position the boot, sterile water may be used as a lubricant.

5. Place non-absorbable sutures around both ends of the boot in the channeled areas of the connection (Figure 26).

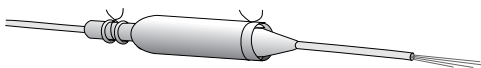


Figure 26. Suture lead/extension.

 **Caution:** Do not overtighten suture because damage may occur to either the boot or the lead.

6. Place the lead/percutaneous extension connection into a small pocket made near the incision site.

7. Close the incision site and stab wound, leaving the fine percutaneous extension wires and pin connector protruding from the skin.

Perform Interoperative Stimulation Test

The following procedure provides instructions on how to connect the percutaneous extension to the test stimulator and begin interoperative test stimulation.

1. Check that the test stimulator output (Amplitude) is Off.
2. Connect the pin connector on the percutaneous extension into the twist-lock connector on the screening cable and the plug end of the cable to the Model 3625 Test Stimulator. Refer to "Test Stimulation with the Twist-Lock Screening Cable" on page 28 for instructions on connecting and disconnecting the twist-lock cable and the test stimulator.

Note: Different electrode configurations should be evaluated at various parameter settings (Rate, Amplitude, Pulse Width).

3. When finished with interoperative test stimulation, turn the test stimulator Off.
4. Unlock the cylindrical twist-lock connector and remove the connector handle.

Removing the Percutaneous Extension

For each implanted lead:

1. Withdraw the external segment of the percutaneous extension approximately 1 cm (0.4 in.) from where it exits the skin (Figure 27).

 **Caution:** Use gentle traction on percutaneous extension to avoid dislodging the lead.

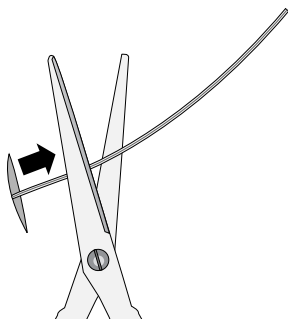


Figure 27. Withdraw the external segment of the percutaneous extension.

2. Sever and discard this section of extension.
3. Locate the lead's percutaneous extension connector at the proximal end of the lead and make an incision to expose it. Allow room to hold the lead firmly to prevent dislodgement.

Note: If an identifying mark was not made when the lead was implanted, probe the area with the fingers or use fluoroscopic observation.

4. Cut the suture and the connector boot over the setscrews to expose the setscrews (Figure 28).

 **Caution:** Do not cut near lead when removing suture from percutaneous extension. Cutting lead's insulation can result in loss of stimulation and lead failure.

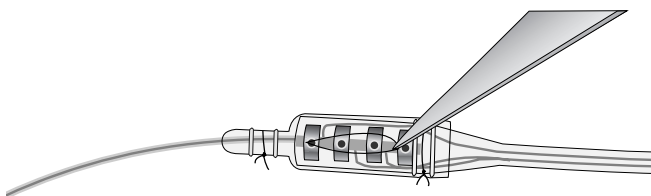


Figure 28. Cut the suture and connector boot to expose setscrews.

5. Using the hex wrench, loosen each of the four setscrews in the setscrew connector by turning the wrench counterclockwise (approximately one turn).
6. Gently remove the lead from the setscrew connector.

 **Caution:** If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrews slightly to ensure that they clear lead contacts. Avoid disengaging setscrews. Inspect lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal.

7. Hold the setscrew connector and withdraw the percutaneous extension through the incision (Figure 29) and discard.

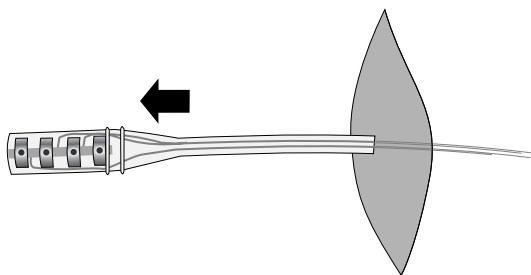


Figure 29. Withdraw percutaneous extension.

8. Remove the boot from the lead and discard the boot.
9. Repeat steps 1 through 8 for other lead if applicable.

Postoperative Patient Management

The treating clinician(s) should be experienced in all aspects of the medical management of patients with Parkinson's disease or Essential Tremor. Clinicians using Activa Therapy for the first time are encouraged to contact a Medtronic representative for information on the postoperative management of Activa patients.

When programming stimulation parameters, give consideration to the following programming recommendations regarding initial stimulation parameters.

Programming Initial Stimulation Parameters for Activa Parkinson's Control Therapy

The following procedure provides instructions on programming post-operative stimulation parameters for Activa Parkinson's Control Therapy, and is one approach for the physician's consideration.

Note: High amplitude/pulse width combinations can result in excessive charge density. Refer to "Programming the Neurostimulator" on page 42 for more information.

1. Allow sufficient time for the patient to recover from surgery. Schedule the initial programming visit so that the patient is in an "off" period, when the Parkinson's disease symptoms are predominant.
2. Set the neurostimulator to the initial settings provided in Table 4.
3. To evaluate the potential effectiveness of all four electrodes, select a predominant Parkinson's disease symptom, such as rigidity or tremor, that responds to changes in stimulation.

Table 4. Programming Settings for Activa Parkinson's Control Therapy

Parameter	Typical Initial Setting	Range/Options	Typical Final Setting
Amplitude (in volts or V)	0.0	Normal 0-10.5 V in 0.115 V steps	2.5-3.5 V
Pulse Width (in microseconds or μsec)	60-120	60-450 in 30 μsec steps	60-120
Rate (in pulses per second or Hz)	130-160	2-185	130-185
Electrode Polarity	Unipolar (Case positive 0 lead electrode negative)	Unipolar or Bipolar	Varies ^a
Mode	Continuous		Continuous

^a In the Medtronic-sponsored clinical investigation, most STN patients used unipolar stimulation, whereas similar proportions of GPi patients used unipolar and bipolar stimulation.

4. To expedite electrode selection, program the neurostimulation system to a unipolar electrode configuration, where the neurostimulator case is the positive electrode, and electrode 0 is the negative electrode.

Note: It may be desirable to ultimately program the neurostimulation system to a bipolar electrode configuration, where both the positive and negative electrical poles are the lead electrodes. This can reduce the potential for electromagnetic interference-related side effects, and may optimize battery life.

5. Gradually increase amplitude by 0.1 - 0.5 V incrementally until a predominant Parkinson's disease symptom (rigidity, tremor) is suppressed. **Do not exceed 3.6 volts.** Wait a few minutes to assess the effect of stimulation.
6. If there is uncomfortable stimulation or inadequate symptom suppression, reduce the amplitude to 0 V and select another electrode as the negative electrode. Repeat step 5. Select the electrode that provides the best control of symptoms with the fewest side effects.
7. After the most desirable negative electrode is selected, gradually increase the amplitude until side effects occur. The therapeutic window between symptom suppression and occurrence of side effects should be sufficiently wide to allow for future amplitude adjustments.
8. Evaluate the patient in an "on" period, when Parkinson's disease symptoms are controlled after a usual dose of antiparkinsonian medication. Assess the effect of stimulation on suppressing or worsening of dyskinesias.

- After Amplitude settings are determined, adjust Pulse Width and Rate to improve therapeutic benefit and minimize side effects.

Note: Symptom suppression is desirable at the lowest possible amplitude, rate, and pulse width in order to improve battery longevity, and minimize charge density.

- Document final parameter settings for future reference.

Programming Initial Stimulation Parameters for Activa Tremor Control Therapy

The following procedure provides instructions on programming post-operative stimulation parameters for Activa Tremor Control Therapy and is one approach for the physician's consideration.

- Allow sufficient time for the patient to recover from surgery.
- Set the neurostimulator to the initial settings provided in Table 5.
- Program the neurostimulation system to a bipolar electrode configuration, where electrode 0 is the negative electrode and electrode 3 is the positive electrode.

Table 5. *Programming Settings for Activa Tremor Control Therapy*

Parameter	Typical Initial Setting	Range/Options	Typical Final Setting
Amplitude (in volts or V)	0.0	Normal 0-10.5 V in 0.115 V steps	1-3 V
Pulse Width (in microseconds or μsec)	60	60-450 in 30 μsec steps	60-90
Rate (in pulses per second or Hz)	130	2-185	130-185
Electrode Polarity	Bipolar 0 electrode negative 3 electrode positive Case off	Unipolar or Bipolar	Bipolar
Mode	Continuous		Continuous

- Gradually increase amplitude by 0.1 - 0.5 V until the occurrence of uncomfortable stimulation or the suppression of tremor is observed. **Do not exceed 3.6 volts.**
- If there is uncomfortable stimulation or inadequate tremor suppression, reduce the amplitude to 0 V and select another electrode as the negative electrode. Repeat step 4. Select the electrode that provides the best control of tremor with the fewest side effects.

6. After the desirable negative electrode is selected, gradually increase the amplitude until side effects occur. The therapeutic window between tremor suppression and occurrence of side effects should be sufficiently wide to allow for future amplitude adjustments.
7. After Amplitude settings are determined, adjust Pulse Width and Rate to improve therapeutic benefit and minimize side effects.

Note: Tremor suppression is desirable at the lowest possible amplitude, rate, and pulse width in order to improve battery longevity, and minimize charge density.

8. Document final parameter settings for future reference.

Note: It may be desirable to program the neurostimulation system to a bipolar electrode configuration, where both the positive and negative electrical poles are the lead electrodes. This can reduce the potential for electromagnetic interference-related side effects, and may optimize battery life.

Programming the Neurostimulator

When programming stimulation parameters, give consideration to the following recommendations regarding charge density and charge imbalance.

Charge Densities – A survey of literature regarding electrical stimulation of neural tissue suggests that damage may occur above 30 microcoulombs/cm²/phase. The Activa System is capable of producing charge densities in excess of 30 microcoulombs/cm²/phase (Figure 30).

The device's maximum amplitude is 10.5 V, and maximum pulse width is 450 microseconds. The curved lines in Figure 30 represent a charge density of 30 microcoulombs/cm²/phase at various impedance measurements, calculated for the electrode surface area of the Model 3387/3389 DBS Lead. Mean resistance found in the clinical studies were as follows.

- Tremor clinical studies (Vim): 1348 ohms (range: 610-2000 ohms).
- Parkinson's disease clinical studies (all targets): 1226 ohms (range: 411-4000 ohms).
- Parkinson's disease clinical studies (GPi): 1079 ohms (range: 411-3300 ohms).
- Parkinson's disease clinical studies (STN): 1285 ohms (range: 529-4000 ohms).

Charge density is determined by plotting a point corresponding to the pulse width setting (x-axis), and the amplitude setting (y-axis). If this point is below the appropriate resistance curve, then the charge density is below 30 microcoulombs/cm²/phase. Points above the curve indicate a charge density above 30 microcoulombs/cm²/phase.

The shaded area of Figure 30 indicates a charge density above 30 microcoulombs/cm²/phase at the conservative impedance estimate of 500 ohms. If stimulation parameters are selected that fall into the shaded area of the graph, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE. CONSULT TECH MANUAL. PRESS CLEAR TO CONTINUE.** Programming may continue at the desired values by pressing the **CLEAR** key. Refer to the appropriate MemoryMod software applications manual for further information.

Figure 30 and Figure 31 include two examples of charge density calculated for the Activa System. In Example A in each figure, the Soletra Model 7426 Neurostimulator is set to: amplitude = 3.0 V and pulse width = 90 μsec. The charge density for Example A is below the shaded warning zone, thus indicating a charge density below 30 microcoulombs/cm²/phase at the most conservative impedance of 500 ohms.

In Example B in each figure, neurostimulator stimulation parameters are set to: amplitude = 6.1 V and pulse width = 210 μsec. The charge density at these settings is in the shaded area indicating it may be high enough to cause tissue damage at an impedance of 500 ohms. However, as shown in Figure 30 and Figure 31, if the impedance in this case is at the clinical mean from either the tremor clinical study or the Parkinson's disease clinical studies, the charge density would be below 30 microcoulombs/cm²/phase.

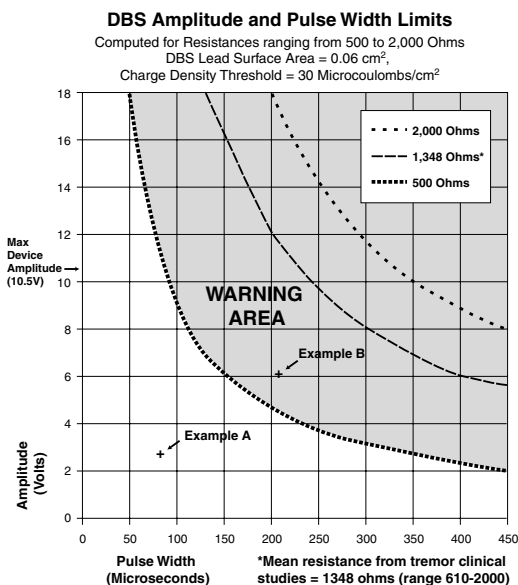


Figure 30. Charge density with tremor clinical mean resistance.

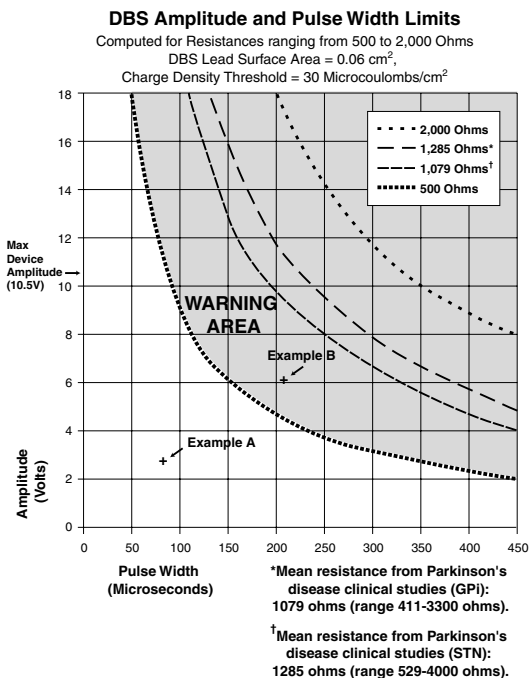


Figure 31. Charge density with Parkinson's disease clinical mean resistance.

Charge Imbalance Condition – For certain neurostimulator stimulation parameter settings the device can produce a **CHARGE IMBALANCE CONDITION**. Charge imbalance may occur when the circuit does not recover the total negative charge that is produced by the On activations. If the charge imbalance (net DC current) exceeds 1.5 μ amps average current, tissue damage may occur. When programming the Itrel II Model 7424 or the Soletra Model 7426 Neurostimulator, the following operating conditions should be observed to remain below the 1.5 μ amps average current:

- **Cycling Mode.** **DO NOT PROGRAM** the Soletra Model 7426 Neurostimulator or the Model 7424 Itrel II Neurostimulator to cycling mode for Activa Therapy. This warning **INCLUDES** the “Special Ramp Stimulation Mode.”
- **SoftStart/Stop.** In this feature, when the device is initially turned On, the voltage is incremental until it reaches the patient's programmed voltage. Each increment is considered an On activation. When programming the Neurostimulator using the SoftStart/Stop feature, refer to Table 6 for aid in programming therapy stimulation. Check the amplitude setting and the pulse width setting. The neurostimulator should **not** exceed the number of activations listed for the selected parameters. An activation occurs when the neurostimulator is turned On and Off by either the patient magnet or the programmer.

More than 50,000 activations in a 24-hour period would be required to generate a charge imbalance condition using typical settings for symptom suppression (frequency = 185 pps, amplitude = 3.0 V, and pulse width = 90 μ sec). A patient typically turns their neurostimulator On in the morning, and Off at night; this counts as one device activation.

Table 6. Maximum Allowable Device Activations^a Per 24-Hour Period. (For all programmable rates and electrode combinations, SoftStart ON)

Programmed Amplitude (volts)	Device Activation Per 24 Hour Period Programmed Pulse Width 60 μ sec	Device Activation Per 24 Hour Period Programmed Pulse Width 90 μ sec	Device Activation Per 24 Hour Period Programmed Pulse Width 120 μ sec	Device Activation Per 24 Hour Period Programmed Pulse Width 150-210 μ sec	Device Activation Per 24 Hour Period Programmed Pulse Width 270-330 μ sec	Device Activation Per 24 Hour Period Programmed Pulse Width 400-450 μ sec
0.0-0.1	135,000	135,000	135,000	135,000	135,000	81,000
0.2-1.0	101,000	73,000	73,000	32,000	23,000	13,000
1.1-2.0	81,000	50,000	50,000	17,000	6,500	4,200
2.1-3.0	54,000	50,000	32,000	7,600	3,200	1,800
3.1-3.6	54,000	30,000	19,000	5,600	2,200	1,000
3.7-4.0	29,000	16,000	12,000	5,000	2,200	1,000
4.1-5.0	22,000	13,000	8,300	2,500	1,100	600
5.2-6.0	16,000	8,900	5,500	1,600	580	300
6.1-6.5	14,000	7,800	5,000	1,200	380	200
6.7-7.2	12,000	6,600	3,500	840	240	140
7.4-8.0	10,000	6,200	3,200	840	240	140
8.2-9.0	8,800	4,600	2,500	570	200	120
9.1-9.5	7,900	4,000	2,100	430	160	110
9.7-10.0	7,600	3,500	1,800	330	130	100
10.1-10.5	6,700	3,100	1,500	260	110	90

^a An activation occurs when the neurostimulator is turned On and Off by either the patient magnet or the programmer.

Physician Training Information

Prescribing physicians should have expertise in the medical treatment of patients with movement disorders. Implanting physicians should have expertise with functional stereotactic neurosurgical treatment of movement disorders. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the targeted nucleus, surgical and /or implantation techniques for the Activa System, operational and functional characteristics of the Activa System, and experience in the continued management of patients by stimulation parameter adjustment. Physicians may contact Medtronic before prescribing or implanting an Activa System for the first time and request a referral to a physician experienced in the use of Activa Therapy.

All Activa System programming should be by or under the supervision of a physician or other experienced medical personnel familiar with the use of the programming software and equipment. Physicians should be thoroughly familiar with Activa System supporting material, including:

- All product labeling, and
- Education and training materials.

Patient Counseling Information

Before surgery, the patient and family should be advised of the known risks of the surgical procedure and the therapy, as discussed in other sections of this manual, as well as the potential benefits. After the Activa System is implanted, the patient should also be advised to read the patient manual included in the neurostimulator package.

Theft Detectors and Screening Devices

Patients should be advised to use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores) because these devices can turn on or turn off their neurostimulator. If an airport security wand is used, they should ask the security personnel to avoid placing the wand over the neurostimulator.

When approaching these devices, patients should do the following:

1. If security personnel are present, show them the neurostimulator identification card and request a hand search.
2. If patients must pass through the security device, they should approach the center of the device and walk normally (Figure 32).
 - a. If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
 - b. If one gate is present, they should walk as far away as possible from it.

Note: Some theft detectors may not be visible.

3. Proceed through the security device. Do not linger near the device.

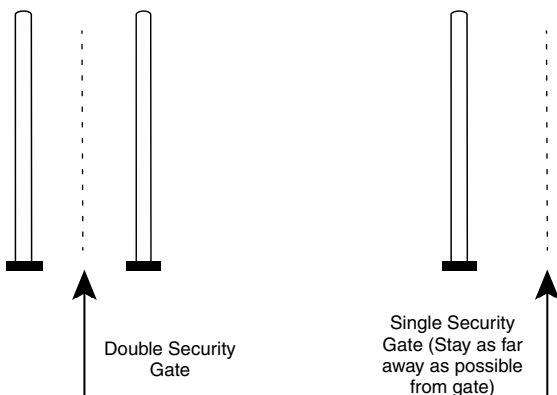


Figure 32. Approaching security gates

4. If patients suspect that their neurostimulator was turned off, they should make sure someone is able to turn on the system again. (This person could be the patient, if their medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Component Manipulation by Patient

Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage.

Detailed Device Description

Lead Materials

A review of the materials, additives and potential breakdown products used in the DBS Leads resulted in identification of two chemicals of concern, including:

- A potential breakdown product of polyurethane is a known animal carcinogen.
- A tin compound is an additive to polyurethane. Some tin compounds are known neurotoxins.

The amount of these compounds released from the DBS Lead over time is unknown.

Note: Each material composing the DBS Lead has been selected for biocompatibility through laboratory testing, animal testing, and clinical experience. The lead and accessories contained in the lead kits are intended for **Single Use Only**.

Lead Specifications

Lead length	10-50 cm
Lead shape	Straight
Lead body diameter	1.27 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical
Electrode length:	
3387 Lead	1.5 mm
3389 Lead	1.5 mm
Electrode spacing (edge to edge):	
3387 Lead	1.5 mm
3389 Lead	0.5 mm
Number of conductor wires	4
Material:	
Conductor wire	Platinum/Iridium
Proximal connector sleeves	Nickel alloy (MP35N)
Stimulating electrodes	Platinum/Iridium
Insulation:	
Conductor wires	Fluoropolymer
Outer jacket tubing	80A Urethane
Conductor resistance	< 100 Ω
Stylet material	Tungsten
Materials in contact with human tissue ^a	Platinum/Iridium 80A Urethane Nylon Silicone

^a Includes implanted accessories.

Notes:

- The electrical resistance of leads is proportional to their length. Very long leads have an increased resistance, which may limit pulse amplitude at the electrodes.
- All dimensions are approximate.

How Supplied

Contents of Package

The Medtronic Model 3387 or Model 3389 DBS Lead Kit consists of the following:

Lead:

- One Model 3387 or 3389 Lead

Accessories:

- Straight stylet (inserted in lead)
- Hex wrench
- Percutaneous extension
- Short stylet
- Screening cables
 - Alligator clip screening cable
 - Twist-lock screening cable
- Depth stop gauge (lead)
- Burr hole ring and cap
- Connector boot
- Stainless steel PERCUPASS II Tunneling Tool and Tunneling Tip
- Polytetrafluoroethylene tubes (straws)

Note: The contents of the inner package are **STERILE** and **NON-PYROGENIC**.

Special Notice

Medtronic lead kits consist of leads and tools to connect the lead to implantable extensions. Leads are used with extensions, which are implanted in the extremely hostile environment of the human body. The warranties and disclaimers for extensions are discussed separately in the packaging information for extensions. Leads may fail to function for a variety of causes, including but not limited to, medical complications, body rejection phenomena, or failure by breakage or by breach of their insulation covering. In addition, leads and tools may easily be damaged by improper handling or use. For tools, Medtronic disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct incidental or consequential damages caused by any defect, failure or malfunction of any tool, whether a claim for such damage is based upon warranty, contract, tort or otherwise. No person has any authority to bind Medtronic to any representation or warranty with respect to tools.

Appendix: MRI and Activa Therapy

Activa Clinical Experience

Due to the variability of clinical MRI systems, the safety of patients or the functioning of devices exposed to MRI systems cannot be unequivocally ensured. However, 39 patients in the Medtronic-sponsored clinical study with an implanted Activa System have safely undergone 1.5 Tesla MRI procedures. These patients were implanted with the Itrel II Model 7424 Neurostimulator, the Model 7495 Extension, and the Model 3387/3389 DBS Lead. For comparison purposes, the Activa System comprising the Soletra Model 7426 Neurostimulator, the 7495/7482 Extension, and the 3387/89 DBS lead is expected to have similar outcomes.

- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.

To validate the in-vitro information regarding safety and efficacy, patient medical records were reviewed at four North American centers that participated in the Medtronic-sponsored clinical investigations of Activa therapies. These centers had 39 patients who underwent a total of 55 MRI procedures with implanted components of the Activa System. At least one neurostimulator was in place for 27 of these procedures.

The MRI procedures were used to verify lead implant within the target (40 procedures); to assess other medical conditions (7 procedures); to localize the brain target contralateral to an implanted lead or to replace a lead (8 procedures). There were no reported adverse events associated with MRI procedures used in conjunction with the implanted Activa lead, regardless of implantation of extensions and neurostimulators.

Risks of MRI and Activa Safety Results

The potential risks of performing MRI on patients with implanted neurostimulation systems and the specific safety information related to the Activa System include:

- Magnetic field interactions and mechanical forces
- Heating effects around the neurostimulator or lead electrodes from Electromagnetic Interference (EMI)
- Inadvertent reed switch activation from magnetic fields
- Neurostimulator damage
- Image distortion and artifacts

Magnetic Field Interactions and Mechanical Forces

Potential Risk: The neurostimulator may experience mechanical forces within or near the static magnetic field of the MRI system due to small amounts of magnetic material contained in the neurostimulator. This may cause the neurostimulator to move within the implant pocket and/or may place mechanical stress on tissues and/or the lead. Compromised tissues (such as recently sutured tissue) may be susceptible to further injury from these forces. Patients may feel a tugging sensation at the site of the neurostimulator implant.

Summary of Test Results: Implanted leads and extensions should not experience magnetic field related mechanical forces since they are made from non magnetic material. Based on MRI safety testing conducted using an MRI system with a static magnetic field of 1.5 Tesla, patient-equivalent phantoms and various device configurations, the magnetic forces acting on the Activa neurostimulator are less than the force of gravity.

Heating Effects

Potential Risk: As with many biomedical implants (e.g. joint replacements, spinal fixation rods, etc.), heating associated with MRI may occur in the Activa System. Tissue damage is a risk because of the potential for temperature rise in the system.

Summary of Test Results: To date, no clinically significant heating has been reported in patients with Activa Systems in the Medtronic-sponsored clinical investigations. Clinically significant heating of up to 15° C was observed in a patient-equivalent phantom during testing in a 1.5 Tesla MRI. To minimize heating the recommendations in “MRI Operation/Settings” on page 56 must be followed.

Inadvertent Reed Switch Activation/Electromagnetic Interference (EMI)

Potential Risk: The magnetic fields of the MRI may activate the magnetic reed switch within the neurostimulator. This may cause the neurostimulator to switch between On and Off (in addition, the Model 7424 Itrel II Neurostimulator may also switch between normal and Mag Amp modes). The MRI gradient and/or RF fields could cause extraneous electrical current to be induced through the lead/extension that the patient may feel.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that the neurostimulator reed switch may be activated by the MRI resulting in on/off switching of the neurostimulator (or also for Itrel II, changing between Normal and Mag Amp modes). In the Medtronic-sponsored clinical trial, there were no reports of shocking or jolting resulting from induced voltages on the lead system.

Neurostimulator Damage

Potential Risk: Induced voltages on the lead/extension system could damage the electronic circuitry and result in a nonfunctioning neurostimulator, requiring replacement. Induced voltages could also cause the neurostimulator to lose its programmed parameter values, which would require subsequent reprogramming. In addition, the neurostimulator could lose its serial number, which cannot be reprogrammed by the physician programmer but does not affect therapeutic use of the neurostimulator.

Summary of Test Results: Medtronic-sponsored in-vitro testing using a 1.5 Tesla MRI system (GE Signa 1.5T) did not result in damage or reprogramming to the Activa neurostimulator or associated leads and extensions.

Image Distortion and Artifacts

Potential Risk: The neurostimulator and lead/extension may distort the MRI image or cause artifacts that may block viewing of tissue located near them.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that there may be substantial image distortion or artifacts near the DBS lead system and neurostimulator. Proper selection of various imaging parameters, while not exceeding the recommendations in “MRI Operation/Settings” on page 56, will help reduce image distortion or artifacts.

MRI Guidelines

Pre-MRI Preparation

Because of the need to change the operating parameters for the Activa System, an appropriate health care professional with access to a Medtronic neurological physician programmer should assist and prepare the patient with this device for the MRI procedure.

- If the neurostimulator has already been implanted, record the patient's current therapeutic settings, set the neurostimulator amplitude to 0 volts (normal and magnet amplitude for the Model 7424 neurostimulator) and turn the neurostimulator output to Off.
- Disconnect all external leads (screening cables) from any percutaneous extensions. Any parts of the percutaneous extensions that exit the body should be wrapped in a thermally and electrically insulating material of approximately 0.5-inch thickness or greater. These coils/leads should be kept out of contact with the patient's skin to avoid the risk of thermal burns from RF energy.
- Instruct the patient to alert the MRI system operator of any problems (heating, shocks, etc) so the operator can terminate the MRI procedure if needed.



Caution: An MRI procedure should not be performed in a patient with an Activa System that has a broken lead wire because tissue damage may result from localized heating at the break. If a broken lead wire is suspected, lead impedance should be checked on all electrodes in unipolar mode. If any electrode impedance is > 2000 ohms and battery current is $< 10 \mu\text{A}$, then an x-ray should be obtained prior to an MRI to verify the presence of a broken wire.

Implant Recommendations

- Implant the minimum length lead and extension possible to minimize induced RF voltage in the lead system.
- Avoid, if possible, implanting the neurostimulator in the abdomen. This requires the use of longer length leads/extensions that can increase the amplitude intensity of the induced RF voltage on the lead system.

MRI Operation/Settings

- Use only MRI systems operating at a static magnetic field strength of 1.5 Tesla.
- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.
- Carefully perform continuous verbal and visual monitoring of the patient throughout the MRI procedure.
- Discontinue the MRI if the patient experiences any pain or discomfort, or if you observe heating or other problems with the implanted components.

Post-MRI Recommendations Operation/Settings

- Verify the neurostimulator is functional.
- Reprogram the stimulation parameters to pre-MRI values.



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